Exhibit 5

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

Alliance for Hippocratic Medicine, *et al.*, Plaintiffs, v. U.S. Food and Drug Administration, *et al.*, Defendants.	Case No. 2:22-cv-00223-Z

DECLARATION OF NIKKI B. ZITE, MD, MPH

I, Nikki Zite, pursuant to 28 U.S.C. § 1746, declare under penalty of perjury that the following is true and correct to the best of my knowledge and belief, and that these statements are based on my personal knowledge as well as information made known to me in the course of my medical practice:

1. I am a board-certified Obstetrician-Gynecologist ("Ob-Gyn") physician and attending physician at the University of Tennessee Graduate School of Medicine in Knoxville, Tennessee. I also serve as the Vice Chair of Education and Advocacy and am a Professor within the Department of Obstetrics and Gynecology. I am board-certified in both the specialty of Ob-Gyn and the Subspecialty of Complex Family Planning by the American Board of Obstetrics and Gynecology (ABOG). In my day-to-day practice, I participate in both inpatient and outpatient management of pregnancies, which includes treating patients undergoing pregnancy loss and other complications that arise during pregnancy, as well as other pregnancy-related emergencies. Our hospital is a Regional Perinatal Center which means that we provide care for high-risk maternal and infant patients transferred from around East Tennessee, Southeastern Kentucky, and Western North

Carolina. Although at my institution we have an emergency room staffed by Emergency Physicians, it is routine for them to call an OB-GYN whenever a patient presents with a miscarriage or bleeding in pregnancy, and we would see the patient if she needed any intervention. If a patient was sent by an abortion clinic, the OB-GYN team would be aware and care for her. So my service line would very likely be made aware of all women presenting with abortion complications, whether the patient freely admitted she had undergone a medication abortion or simply presented with signs of a spontaneous miscarriage.

2. I graduated from Northwestern University Medical School in Chicago, Illinois in 1998, and completed my residency in Memphis at the University of Tennessee Health Science Center in 2002. I completed my Complex Family Planning Fellowship and my Master's in Public Health at the University of Illinois at Chicago in 2004. I have been affiliated with the University of Tennessee Graduate School of Medicine in Knoxville since 2004, with a leave of absence in 2008-2009 when I worked at the Cleveland Clinic in Cleveland, Ohio, while my husband completed his fellowship.

3. In my current position, I have been active in teaching obstetrics to residents, fellows, and medical students. I served as the Residency Program Director for 10 years before becoming the Vice Chair of Education and Advocacy. I am a researcher with National Institutes of Health funding and more than 50 publications. I am currently the Treasurer of the Tennessee Section of the American College of Obstetricians and Gynecologists (ACOG). I am also on the ACOG Contraceptive Equity Expert Workgroup. I was on the Board of Directors for the Society of Family Planning for 10 years and have been on their clinical guidelines committee for almost as long. This committee reviews and publishes evidence-based guidance on abortion. I was on the content expert panel that created the ABOG Complex Family Planning board certification exam. I have

over 18 years of experience as a clinician, researcher, advocate, and educator. In these roles, I have delivered or supervised the deliveries of too many babies to count and trained countless students and residents.

4. I am familiar with the medication Mifepristone and have used it in the course of my practice. Even before Tennessee enacted its strict abortion ban, which went into effect August 25, 2022, our hospital policy allowed abortion only under very narrow circumstances.

5. In the cases that did occur at our medical center, prior to prescribing mifepristone, legal and medical ethics require providers, such as myself, to ensure that appropriate informed consent is obtained and that shared decision-making is effectuated with the patient and her family members, if she chooses. Further, for mifepristone, it was my hospital's and my personal policy to provide the manufacturer's medication guide and the patient agreement form as required by the mifepristone REMS.

6. The information I provide to my patient is based on my years of training and experience both teaching new doctors and treating patients, as well as my reading of the extensive research on this topic. I understand that all medications and medical procedures carry risks, including rare adverse events, and convey that understanding to patients as part of my regular medical practice. Evidence and my personal experience treating pregnant people and pregnancy-related emergencies nevertheless demonstrate that the combination of mifepristone with misoprostol is both safe and effective for medication abortion. Serious complications, like the need for blood transfusions or hospitalizations, are incredibly rare (less than 1%).

7. Although the policies of the UT Medical Center preclude its doctors from being employed by outpatient abortion clinics, our residents complete rotations at Knoxville Center for Reproductive Health ("Knoxville Center") and Planned Parenthood – Knoxville Health Center

("Planned Parenthood") to meet the Accreditation Council for Graduate Medical Education Obstetrics and Gynecology educational requirements for abortion training. Our institution provides back-up for the rare times their patients required after-hours care, separate and apart from whether a resident currently was completing a rotation at one of these clinics. Complications, sometimes called adverse events, from all abortion, including medication abortion, are rare. At no time did our institution feel that caring for patients from these clinics after hours or if they had a rare complication strained our residency training program or our ability to care for other patients.

8. For most of the last two decades, as various federal and state regulations have changed, I have been in a position to observe any trends concerning patients presenting with mifepristone-related adverse events from these clinics. For instance, when I started practicing at the University of Tennessee Medical Center in 2004, mifepristone could be prescribed for a medication abortion under the original REMS, and in fact, it was prescribed by Planned Parenthood and Knoxville Center for abortions. I have continued to see the same general patient population through FDA's revision of the REMS in 2016, which extended the gestational age limit from 49 days to 70 days and reduced the number of required in-person visits from three to one. I have also continued to see the same general patient population after FDA's approval of a mifepristone generic in 2019 and after FDA's temporary elimination of the in-person dispensing requirement in 2021. There has been no appreciable difference in the volume or severity of patients obtaining care in our emergency department after medication abortion over this time period, despite an increase in volume at the Knoxville area abortion clinics. On the contrary, it has continued to be the case that complications from medication abortion are exceedingly rare and, when they occur, can be promptly treated.

I understand that Knoxville Center provided 300-350 patients with medication abortion annually before the 2016 REMS change that allowed use up to 70 days gestation, and then between 600-650 per year from 2016 until the *Dobbs* Decision and the enactment of state-level abortion bans in 2022. Planned Parenthood estimated that they performed approximately 800 medication abortions per year before 2016, and 1000 per year after. At my institution, despite the increase in volume of medication abortion in our area after the 2016 REMS changes, we did not experience a significant change in volume of patients with either miscarriage or abortion complications. (As noted above, rare adverse events from medication abortion present with the same clinical signs as spontaneous miscarriage, so a provider does not know a patient has ingested Mifepristone or Misoprostol unless she discloses that information.) At no time since I have worked in Knoxville has caring for abortion complications interfered with our ability to care for other patients suffering complications of pregnancy or from other traumas. Similarly, at no time since I have been in Knoxville have women hemorrhaging in early pregnancy or from complications of medication abortion threatened our blood supply.

9. I have also continued to practice and see the same general patient population through various iterations of Tennessee's state abortion laws, including requirements that abortion providers possess admitting privileges. During this timeframe, Planned Parenthood and Knoxville Clinic partnered with my hospital to continue to train our residents, and thus, their patients were directed to present to our hospital with any complications from taking mifepristone.

10. In my experience, I did not perceive or hear of a rise in the rate of patients presenting with adverse events purportedly related to mifepristone as FDA revised the REMS to expand the availability of mifepristone. In fact, my experience aligns with FDA's findings regarding mifepristone's safety and efficacy in that I have rarely encountered patients experiencing adverse

events due to mifepristone use. And I have never believed that treatment of such patients consumed significant time or resources such that I was not able to provide the appropriate care and attention to my other patients. On the contrary, in the exceedingly rare instances when a patient presents with complications from a medication abortion, we are able to provide any indicated treatment promptly and relatively easily. Given that the complications from medication abortion are identical to those from miscarriage, our residents gained knowledge about potential complications from their abortion rotations, but were more likely to use the knowledge and skills treating spontaneous pregnancy loss than an induced abortion complication.

11. I understand that Plaintiffs in this suit have asked the Court to revoke FDA's approval of Mifepristone based, in part, on certain physicians' claims that mifepristone and various revisions to the REMS have created a greater danger to people seeking to terminate their pregnancies. These declarations are inconsistent with my own experience as a practicing physician and scholar. Specifically, with my work on the Society of Family Planning Clinical Guideline Committee, I have never reviewed scientific literature that suggests abortion has become less safe since Mifepristone has been available or with any of the REMS changes. Given that, based on my experience, it is my view that women will always find a way to access abortion, medication abortion has made abortion safer. And in the absence of medication abortion, I expect to see worse outcomes among my patient population.

12. First, I have reviewed the declaration of Dr. Mario R. Dickerson. He states that the "approval of mifepristone … and subsequent elimination of certain safeguards for the use of [mifepristone], including those found in the Risk Evaluation and Mitigation Strategy … has led to an increasing risk that women and girls may suffer adverse events from chemical abortion." Dickerson Decl. ¶ 11. He goes on to assert that certain OB/GYNs and emergency department

physicians treat patients suffering from adverse events supposedly caused by mifepristone, such as heavy bleeding, severe pain, hemorrhage and sepsis, to such an extent that they "are called away from other patients to render emergency treatment." *Id.* ¶¶ 13-14. As an initial matter, triaging patients based on the need for imminent care is a standard operating principle of any emergency department and OBGYN, and is the reason individuals requiring an emergency cesarean section are seen before those needing a routine labor check. But more importantly, I have not observed any such rise in patients presenting with adverse events related to mifepristone following FDA's revision of the REMS and I am unaware of any such material changes in patient populations observed by my colleagues and acquaintances who practice in my field. In my community, such volume changes would have been observed and treated at my institution and would have been brought to my attention if they were occurring. Although I have never worked at a free-standing abortion clinic, as the only Complex Family Planning subspecialist in East Tennessee, it is well known that if patients were suffering harm from abortion care, I would be the one to reach out to. I have never had an emergency physician or OBGYN from my institution or the community reach out with this concern. These people always knew where to find me if their patients needed an abortion for one of the indications my hospital was able to perform.

13. Second, I have reviewed the declaration of Dr. Donna Harrison. She asserts in her declaration that "[b]ecause the FDA abandoned the post marketing requirement that abortion providers have admitting privileges to handle their own complications … , the predictable consequence is the explosion of Mifeprex complications including hemorrhage, adding to the current shortage of blood and blood products across the United States." Harrison Decl. ¶ 19. This statement is contrary to my experience. As noted above, I have not observed any notable difference in the rate of patients presenting with mifepristone-related adverse events when an admitting-

privileges requirement has been in place versus when it has not been a requirement, and given that the UT Medical Center partnered with Planned Parenthood and Knoxville Center when that requirement was in place, such a distinction would have been notable to my colleagues and me if it existed. Likewise, the number of patients presenting with mifepristone-related complications in my hospital covering parts of three states cannot be said to be responsible for a blood shortage in the Knoxville area. On the contrary, given the demonstrably low rate of complications from the Mifepristone/Misoprostol regimen, it is inconceivable to me that medication abortion could have a measurable impact on the blood supply in any location. Post-partum hemorrhage from term deliveries is a problem being addressed nationally as part of the ACOG Alliance for Innovation on Maternal Health (AIM) quality improvement bundles. *See* ACOG, Alliance for Innovation on Health, *AIM Patient Safety Bundles: Obstetric Hemorrhage*, https://saferbirth.org/psbs/obstetric-hemorrhage/. If hemorrhage or transfusions from medication abortion was a significant issue, ACOG would be addressing it as well.

14. For the same reasons described above in relation to Dr. Dickerson's declaration, I similarly find Dr. Harrison's statement that women presenting with mifepristone-related complications "can overwhelm the medical system" and that such patients "multipl[y] the workload of healthcare providers … in some cases by astronomical amounts" to be unsupported by anything in my experience or study. I have worked at referral centers in Memphis, Chicago, Knoxville and Cleveland, and I have never believed that complications from induced abortion – medical or surgical – created a volume issue for healthcare professionals.

15. As a physician educator, I am familiar with data that demonstrates that residents who are experienced with abortion care are also more comfortable and confident treating miscarriages. *See, e.g.*, Horvath, et al., *Increase in Obstetrics and Gynecology Resident Self-Assessed Competence in*

Early Pregnancy Loss Management With Routine Abortion Care Training, 139 Obstet. Gynecol. 116-11 (Jan. 1, 2022) (I am a senior author on this paper). In my experience, training residents on all aspects of reproductive healthcare best prepares them to take care of women during their most vulnerable times. Revoking approval of Mifepristone would make this job harder.

Dated: January 13, 2023

Nikki B. Zite, MD, MPH